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Cc: ISMTP@FDA-OC-TRAINING@FDAOC["'Mary Wiltshire'" <naa@intrepid.net>]
> Sent: Sunday, January 18, 1998 3:29 PM
> Cc: 'Mary Wiltshire'; 'Betsy Sheehan'
> Subject: Comments - Docket No. 97N-0217
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Proposals to increase the availability of approved animal drugs for minor species and minor uses.

COMMENTS-

General: Thank you for the opportunity to participate and comment. A great deal of work and thought went into this document. I am glad that FDA is concerned about our aquaculture industry. Now that I have said that, let me comment that aquaculture still in many ways is a "minor" business in that we are all small. As a small business we simply do not have the time, and in many cases, the ability to access what is going on with the current regulatory thought concerning our industry. We are simply too busy working and are very dependent upon a few industry volunteers, trade associations, extension, and trade publications to keep abreast of all these regulatory events. Toooften we find out about something after it is a done deal or in the worse case, when something is enforced against one of us.

So while commending FDA for their effort, I suggest that the effort be kept simple, affordable, and understandable for the small producer. For example, in Florida we have about 700 aquatic farmers. Our job is to get the crop grown and to market in an efficient, responsible, and profitable manner. We just need the right tools. Many tools already exist, we need FDA and USDA to make sure they are OK to use and then give us the ability to use them. Producers would rather not use drugs as they add to the expense of production. The FDA opinion on extralabel use not being the answer (AMDUCA) might be overstated. Has FDA actually compiled any data on types and amounts of drugs prescribed by veterinarians in aquaculture. How does the total amounts or use compare with use and totals of other drugs for other purposes, such as humans or one hospital in one major city for one day. Where is the final resting place for all the drugs dispensed in one day's hospital use?

Aquaculture needs government help if these drug issues are this critical. We simply do not have the time or money to commit to solving these issues. We remain an emerging industry and one which will play an increasingly important role in our future food supply. In general, the role of government is to keep up with developments in all segments of the private sector. To do otherwise is against all concepts of our society and free enterprise. And it is the free enterprise system which allows the American government to exist by providing a source of operating funds. Our nation needs a plentiful and safe food supply and the one thing farmers cannot grow is money. Government needs to make decisions, find solutions, and give us the tools necessary to do our job.

A an industry, we do have policy positions. I fully support the drug and drug use policies of the National Aquaculture Association. The recent formation of the Aquatic Animal Health Policy Development Committee along with NAA and Roz Schnick, NADA Coordinator, are excellent

resources for FDA to work with in obtaining new tools for aquaculture. The industry trusts and respects these groups and Ms. Schnick and has great confidence in their ability to help the aquaculture industry.

Specific Comments: Each of the proposals should begin with the questions of whether or not it is needed; will it be used; how easy will it be to use; the amount of time and paperwork required by industry; and will the proposal really make a difference.

A. Modification of extralabel provisions. The environmental concern needs to be viewed in a bigger picture such as the hospital question above or other impacts to the environment. FDA must remember that any new drug will not be cheap and as a result only a recommended preventative treatment or a crisis treatment will cause a use by the farmer. That is, compared to other environmental impacts, this in less than minor. Reproductive hormones and implants should be included especially when used with brood stock animals. The ten year sunset period may be OK but this is where FDA needs to give industry their experience with drug research and approval. What can be accomplished in 10, 15 or 20 years. You tell us.

B. Removal of disincentives. I would rather see our limited funding in aquaculture go toward research and drug approval and not enforcement. I once worked for the government. There are plenty of opportunities to review rules, policies, etc, and get rid of many of them to free up staff time. Give the enforcement folks in letting them do their job (empower them with a equal amount of authority to match their responsibility) and the results will be impressive. What happened to Reinventing Government and A Mandate for Change, both big books on Pres. Clinton's reading list. The old saying "Locks are for honest folks" hold true here. Make penalties stiff for those selling drugs illegally to producers. If a company has not participated in the development/testing whatever of a new drug or paid a licensing fee, then they simply cannot sell it. Also, USDA has lots of veterinarians and they have cured just about all large animal diseases, so they may have time to put towards these enforcement (or education) actions and to serve as the minor use advocate.

C. Enhancement of Existing Programs for Data Development. FDA should note that the programs mentioned (SK, Hatch, NCRI etc) are also important to meet other, non-drug aquaculture research needs. The NRSP-7 program is a very good program and should be expanded. Funding might come from a number of methods. Adding Congressional appropriations is the most straightforward. However, the FDA ideas of tax credits for drug company sponsorship is excellent. Another might be to get a University to participate with the drug company in a joint venture whereby the university scientist (intellectual property) is put up as a funding contribution to the drug company in return for a royalty once the drug comes onto the market. This further makes the university, often a benefactor of tax dollars, part of the risk and thereby creates a greater incentive to succeed.

I am not sure about C.2 for establishing a new program. I think the idea about making better and more efficient use of existing government staff should be used. Again, the ideas of reprioritizing (Reinventing Government) or using USDA vets who have run out of cow patients is worthy of consideration to initiate this new program idea without requiring a new source of funds. The data base is an excellent idea. Greater use of computers- internet and email should help create a larger

data base, greater participation, and hopefully new and less time consuming solutions.

D. Incentives to pursue drug approval. Great idea for both tax incentives and shorter time (quick response/fast track) frame for review and adoption. The competition factor should take care of itself. If the drug company with the extended exclusivity prices the drug too high, then farmers will not buy it and demand additional drugs. That is, it will be in the benefit of both the company and the grower to work together to maintain the profit of both businesses. Yes, give longer exclusivity to the company taking all the risk. The tax break could also be factored into the pricing of the final product- the lower the unit cost per treatment, the greater the tax break or similar scenario.

E. Data Sharing. This sounds like a good idea, but again is one of those things which aquatic farmers do not completely understand or want to know about. If one company gets exclusivity for registering a new drug and another company wants to use the data, then perhaps a fee could be paid by the new company to the one with the data or some other sort of joint venture proposed. Maybe a longer exclusivity period in return for the data may be a solution.

F. Creation by statute of Minor Use Drug Program. Statutory designation of minor use animal drug seems OK, what are the pitfalls? If the statutory designation helps FDA in doing its job, then industry will support. How FDA organizes this is FDA business. No comment.

G. Conditional approval involving non-food animals. The amendment to allow conditional approval of minor use drugs should be supported by industry. Non food animals should be allowed to use unapproved drugs more quickly. FDA should look at extending any of these drugs for use in the following sequence: non-food; newly hatched juveniles; aquatic food animals. The consumer would be adequately protected.

H. Alternative approval standard. This one sounds good, however additional information on the approval process may be needed. A good one to turn over to the Aquatic Animal Health Committee.

I. International Harmonization. This is a good idea and non-governmental input could help in determinations. The differences in standards, etc between US FDA and a foreign FDA agency is something that could be left up to FDA and USDA staff to figure out and make work.

Again, FDA should use the process and policies established by NAA, the Aquatic Animal Health Committee, and NADA coordinator Schnick.

Thanks for the opportunity to provide comments.

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